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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,288	07/06/2001	Paul F. Goetinck	10284-029001 / MGH 1733.1	6095

7590 10/23/2002

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 10/23/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/900,288

Applicant(s)

GOETINCK, PAUL F.9

Examiner

Christopher H Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 12-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 & 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of group I in Paper No. 8 is acknowledged.
2. This application contains claims 12-15 drawn to an invention nonelected without traverse in Paper No. 8. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.
3. Claims 1-15 are pending, claims 12-15 are withdrawn
4. withdrawn from consideration, therefore claims 1-11 are examined on the merits.

Information Disclosure Statement

5. The Information Disclosure Statements filed 1-28-02 and 1-11-02 (paper no. 5 & 6) are acknowledged and considered. A signed copy of the IDS is attached hereto.

Drawings

6. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Claim Rejections - 35 USC § 112

7. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
8. Regarding claims 1, 2, 3, 4, and 7 in the recitation of the term "level", it is unclear as to whether the applicant intends to refer to protein or nucleic acid expression "levels."

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Because the term has not been adequately defined in the specification, the metes and bounds of the term cannot be established.

9. Regarding claims 5 and 6 in the recitation of the phrase "inhibitory form", it is unclear as to whether the naturally occurring ligand or fibronectin has an inhibitory form.

Clarification is required

10. Regarding claim 6, in the recitation of the term "fragment", it is unclear as to which fibronectin fragment is being referred, and because the claim has not specifically recited which fragment is encompassed by the claim, the metes and bounds of the term cannot be established.

11. Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a methods of inhibiting angiogenesis through the generation of a transgenic syndecan-4 null animal but does not reasonably provide enablement for a method of inhibiting angiogenesis through the administration of agents to a patient. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The first paragraph of 35 U.S.C. 112 states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The

courts have further interpreted undue experimentation as requiring “ingenuity beyond that to be expected of one of ordinary skill in the art” (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977) and have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986). Among the factors are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of experimentation needed.

The nature of the invention: The claims of the instant invention are drawn to a method of inhibiting angiogenesis in a subject comprising decreasing syndecan-4 by administering an agent.

The state of the prior art and the predictability or lack thereof in the art: The art teaches that transgenic mice lacking syndecan-4 have delayed wound repair function (see Echtermeyer *et al* J. Clin. Invest. 2000:107:R9-R14). However, nowhere in the art does it teach of the administration of agents, such as nucleic acids molecules, proteins, antibodies or soluble fibronectin fragments that have syndecan-4 inhibitory function.

The amount of direction or guidance present and the presence or absence of working examples: The working examples provided in the instant application are drawn to the

construction of syndecan-4 expression vectors, generation of transgenic mice, and analysis of transgenic mice deficient of syndecan-4. However, no detailed working example is provided that would indicate to one of skill in the art what type, amount, dose, or indications for use of the agent. The mere mention of the general types of agents intended to be used for the method is not enablement enough to teach one of skill in the art what specific agent is needed to perform the instant invention. Although the claims do specifically recite the use of soluble fibronectin fragments for the inhibition of syndecan-4, no mention of how it is used, the amount need for inhibitory function and the identification of a specific inhibitory fragment is provided in the specification.

The breadth of the claims and the quantity of experimentation needed: Given the broad range of agents encompassed within the claims, which includes nucleic acid molecules, proteins, antibodies, soluble inhibitory fragments for which there is no specific teaching or working example, and absent sufficient teachings in the specification to overcome the teachings of unpredictability found in the art, it would require undue experimentation by one of skill in the art to be able to practice the invention commensurate in scope with the claims.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Gallo *et al* (J. Invest. Derm. 1996 Nov ; 107(5):676-683, IDS **AF**) teach that syndecan-4 expression levels are elevated during wound healing in endothelial cells and that expression of syndecan-4 is transient wherein the expression is absent during non-wound healing events.


13. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher Yaen
Art Unit 1642
October 3, 2002



ANTHONY J. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGICAL CENTER 1000